DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, and 524

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for 25 approved new animal drug applications (NADAs) from American Cyanamid to Fort Dodge Animal Health.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: American Cyanamid, Division of American Home Products, P.O. Box 1339, Fort Dodge, IA 50501, has informed FDA that it has transferred ownership of, and all rights and interest in, the following 25 approved NADAs to Fort Dodge Animal Health, Division of American Cyanamid Co., P.O. Box 1339, Fort Dodge, IA 50501:

NADA Number	Trade Name
006–084	SULMET Drinking Water Solution
008–774	SULMET Solution Injectable
011–582	VETAMOX Soluble Powder
011–644	FELAC
013–957	S.E.Z. Drinking Water 6.25%
015–160	Sodium Sulfachloropyrazine Solution
033–342	PROBAN Cythioate Tablets 30 mg
033–606	PROBAN Oral Liquid
033–653	S.E.Z. Drinking Water Solution
033–654	S.E.Z. Oblets 15 g
033–655	S.E.Z. Intravenous Solution
047–033	S.E.Z. C–R Oblets 15 g

NADA Number	Trade Name
055–012	AUREOMYCIN Sulmet Soluble Powder
055–018	AUREOMYCIN Tablets 25 mg
055–020	AUREOMYCIN Soluble Powder
055–039	AUREOMYCIN Soluble Oblets
065–071	AUREOMYCIN Soluble Powder
065–269	POLYOTIC Soluble Powder
065–270	POLYOTIC Oblets
065–313	BACIFERM Soluble 50
065–440	AUREOMYCIN Soluble Powder Concentrate
065–441	POLYOTIC Soluble Powder Concentrate
122–271	SULMET Oblets
122–272	SULMET Soluble Powder
140–844	TRAMISOL Pour-On

Accordingly, the agency is amending the regulations in 21 CFR 520.44, 520.154c, 520.445a, 520.445b, 520.445c, 520.530, 520.531, 520.2184, 520.2240a, 520.2240b, 520.2260a, 520.2261a, 520.2261b, 520.2345c, 520.2345d, 522.940, 522.2240, 522.2260, and 524.1240 to reflect the transfer of ownership and to reflect current format.

Following this change of sponsorship, American Cyanamid is no longer the sponsor of any approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for American Cyanamid.

This rule does not meet the definition of ‘‘rule’’ in 5 U.S.C. 804(3)(A) because it is a rule of ‘‘particular applicability.’’ Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, and 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, and 524 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for ‘‘American Cyanamid’’ and in the table in paragraph (c)(2) by removing the entry for ‘‘010042’’.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.44 [Amended]

4. Section 520.44 *Acetazolamide sodium soluble powder* is amended in paragraph (b) by removing ‘‘010042’’ and by adding in its place ‘‘053501’’.

§ 520.154c [Amended]

5. Section 520.154c *Bacitracin zinc soluble powder* is amended in paragraph (b) by removing ‘‘010042’’ and by adding in its place ‘‘053501’’.

§ 520.445a [Amended]

6. Section 520.445a *Chlortetracycline bisulfate/sulfamethazine bisulfate soluble powder* is amended in paragraph (b) by removing ‘‘010042’’ and by adding in its place ‘‘053501’’.

§ 520.445b [Amended]

7. Section 520.445b *Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate)* is amended in paragraphs (b) and (d)(4)(iii)(C) by removing ‘‘010042’’ and by adding in its place ‘‘053501’’.

§ 520.445c [Amended]

8. Section 520.445c *Chlortetracycline tablets and boluses* is amended in paragraph (b) by removing ‘‘010042’’ and by adding in its place ‘‘053501’’.

§ 520.530 [Amended]

9. Section 520.530 *Cythioate oral liquid* is amended in paragraph (b) by removing ‘‘010042’’ and by adding in its place ‘‘053501’’.

§ 520.531 [Amended]

10. Section 520.531 *Cythioate tablets* is amended in paragraph (b) by removing ‘‘010042’’ and by adding in its place ‘‘053501’’.

§ 520.2184 [Amended]

11. Section 520.2184 *Sodium sulfachloropyrazine monohydrate* is amended in paragraph (b) by removing ‘‘010042’’ and by adding in its place ‘‘053501’’.

§ 520.2240a [Amended]

12. Section 520.2240a *Sulfaethoxypyridazine drinking water* is amended in paragraph (c) by removing ‘‘010042’’ and by adding in its place ‘‘053501’’.

§ 520.2240b [Amended]

13. Section 520.2240b *Sulfaethoxypyridazine tablets* is amended in paragraph (c) by removing ‘‘010042’’ and by adding in its place ‘‘053501’’.

§ 520.2260a [Amended]

14. Section 520.2260a *Sulfamethazine oblet, tablet, and bolus* is amended in paragraph (a)(1) by removing ‘‘010042’’ and by adding in its place ‘‘053501’’.

§ 520.2261a [Amended]

15. Section 520.2261a *Sulfamethazine sodium drinking water solution* is amended in paragraph (a) by removing ‘‘010042’’ and by adding in its place ‘‘053501’’.

§ 520.2261b [Amended]

16. Section 520.2261b *Sulfamethazine sodium soluble powder* is amended in paragraph (a) by removing ‘‘010042’’ and by adding in its place ‘‘053501’’.

§ 520.2345c [Amended]

17. Section 520.2345c *Tetracycline boluses* is amended in paragraph (b) in the first sentence by removing ‘‘010042’’ and by adding in its place ‘‘053501’’.

§ 520.2345d [Amended]

18. Section 520.2345d *Tetracycline hydrochloride soluble powder* is amended in paragraphs (a)(3), (d)(1)(iii), and (d)(2)(iii) by removing ‘‘010042’’ and by adding in its place ‘‘053501’’.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

19. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.940 [Amended]

20. Section 522.940 *Colloidal ferric oxide injection* is amended in paragraph (c)(1) by removing ‘‘010042 and 017800’’ and by adding in its place ‘‘017800 and 053501’’.

§ 522.2240 [Amended]

21. Section 522.2240 *Sulfaethoxypyridazine* is amended in paragraph (c) by removing ‘‘010042’’ and by adding in its place ‘‘053501’’.

§ 522.2260 [Amended]

22. Section 522.2260 *Sulfamethazine injectable solution* is amended in paragraph (b) by removing ‘‘010042’’ and by adding in its place ‘‘053501’’.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

23. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.1240 [Amended]

24. Section 524.1240 *Levamisole* is amended in paragraph (b) by removing ''010042'' and by adding in its place ''053501''.

Dated: November 8, 2002.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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